IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF ALABAMA
NORTHERN DIVISION

DEBRA RUBERTI, Plaintiff, v. ETHICON, INC. and JOHNSON & JOHNSON, Defendants.	)	CASE NO. 2:20-CV-874-WKW [WO]

MEMORANDUM OPINION AND ORDER

Before the court is Defendants' *Daubert* motion to exclude certain general opinions of Plaintiff's expert, Dr. Daniel Elliott. (Doc. # 71-10 at 1–5.)[1] Debra Ruberti (Plaintiff) opposes this motion. (Doc. # 71-15.) For the reasons discussed below, Defendants' motion is due to be GRANTED in part, DENIED in part, and DEFERRED in part.

I. STANDARD OF REVIEW

The admissibility of expert testimony is governed by Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993) (and its progeny). Rule 702 provides:

> A witness who is qualified as an expert by knowledge, skill, experience, training, or education may testify in the form of an opinion or otherwise if:

[1] All citations use the pagination as designated by the CM/ECF filing system.

> (a) the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue;
>
> (b) the testimony is based on sufficient facts or data;
>
> (c) the testimony is the product of reliable principles and methods; and
>
> (d) the expert has reliably applied the principles and methods to the facts of the case.

Fed. R. Evid. 702.

Rule 702 assigns the trial court a gatekeeping role to "ensure that any and all scientific testimony or evidence admitted is not only relevant, but reliable." *Daubert*, 509 U.S. at 589; *see also Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 141 (1999) ("[T]he Federal Rules of Evidence 'assign to the trial judge the task of ensuring that an expert's testimony rests both on a reliable foundation and is relevant to the task at hand.'" (quoting *Daubert*, 509 U.S. at 597)). This gatekeeping responsibility is the same when the trial court is considering the admissibility of "testimony based upon 'technical' and 'other specialized knowledge.'" *Kumho Tire*, 526 U.S. at 141 (quoting Fed. R. Evid. 702).

Considering *Daubert*'s "gatekeeping requirement," the Eleventh Circuit requires district courts to engage in a "rigorous three-part inquiry" for assessing the admissibility of expert testimony under Rule 702:

> Trial courts must consider whether: "(1) the expert is qualified to testify competently regarding the matters he intends to address; (2) the

> methodology by which the expert reaches his conclusions is sufficiently reliable as determined by the sort of inquiry mandated in *Daubert*; and (3) the testimony assists the trier of fact, through the application of scientific, technical, or specialized expertise, to understand the evidence or to determine a fact in issue."

United States v. Frazier, 387 F.3d 1244, 1260 (11th Cir. 2004) (en banc) (quoting *City of Tuscaloosa v. Harcros Chems., Inc.*, 158 F.3d 548, 562 (11th Cir. 1998)). These requirements are known as the "qualification," "reliability," and "helpfulness" prongs. *See id.*

"The burden of establishing qualification, reliability, and helpfulness rests on the proponent of the expert opinion." *Id.* And the proponent must meet its burden "by a preponderance of the evidence." *Boca Raton Cmty. Hosp., Inc. v. Tenet Health Care Corp.*, 582 F.3d 1227, 1232 (11th Cir. 2009); *see also Allison v. McGhan Med. Corp.*, 184 F.3d 1300, 1306 (11th Cir. 1999) ("The burden of laying the proper foundation for the admission of expert testimony is on the party offering the expert, and the admissibility must be shown by a preponderance of the evidence." (citing *Daubert*, 509 U.S. at 592 n.10)).

As to qualifications, "experts may be qualified in various ways," including by scientific training, education, and experience. *Frazier*, 387 F.3d at 1260–61. "Whether a proposed expert's experience is sufficient to qualify the expert to offer an opinion on a particular subject depends on the nature and extent of that experience." *United States v. Cunningham*, 679 F.3d 355, 379 (6th Cir. 2012). "If

the witness is relying solely or primarily on experience, then the witness must explain how that experience leads to the conclusion reached, why that experience is a sufficient basis for the opinion, and how that experience is reliably applied to the facts." Fed. R. Evid. 702 advisory committee's note to 2000 amendments.

Courts must also be mindful that "[e]xpertise in one field does not qualify a witness to testify about others." *Lebron v. Sec'y of Fla. Dep't of Child. & Fams.*, 772 F.3d 1352, 1368 (11th Cir. 2014). "[S]o long as the expert is at least minimally qualified, gaps in his qualifications generally will not preclude admission of his testimony, as this relates more to witness credibility and thus the weight of the expert's testimony, than to its admissibility." *Henderson v. Goodyear Dunlop Tires N. Am., Ltd.*, Nos. 3:11-CV-295-WKW, 3:12-CV-510-WKW, 2013 WL 5729377, at *6 (M.D. Ala. Oct. 22, 2013) (alteration in original) (citation omitted).

As to reliability, trial courts retain "considerable leeway in deciding in a particular case how to go about determining whether particular expert testimony is reliable." *Kumho Tire*, 526 U.S. at 152. The focus of reliability "must be solely on principles and methodology, not on the conclusions that they generate." *Daubert*, 509 U.S. at 595. After all, "*Daubert* does not require certainty; it requires only reliability." *Hendrix ex rel. G.P. v. Evenflo Co.*, 609 F.3d 1183, 1198 n.10 (11th Cir. 2010).

Finally, whether the expert testimony will help "the trier of fact to understand the evidence or to determine a fact in issue" "goes primarily to relevance." *Daubert*, 509 U.S. at 591 (quoting Fed. R. Evid. 702). "Expert testimony which does not relate to any issue in the case is not relevant and, ergo, non-helpful." *Id.* (citation omitted). Moreover, "[o]nce an expert opinion has satisfied *Daubert*, a court may not exclude the opinion simply because it believes that the opinion is not — in its view — particularly strong or persuasive." *Seamon v. Remington Arms Co., LLC*, 813 F.3d 983, 990 (11th Cir. 2016). Where the basis of expert testimony satisfies Rule 702, "[v]igorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." *Daubert*, 509 U.S. at 596.

II. DISCUSSION

The relevant facts have been set out in a prior opinion of this court. (Doc. # 109 at 2–3.) On August 19, 2022, Defendants informed the court that there were pending *Daubert* motions that had not been resolved by the multidistrict litigation (MDL) court—U.S. District Court, Southern District of West Virginia. (Doc. # 118.) Among those pending motions was Defendants' motion to exclude certain general opinions of Daniel Elliott, M.D. (Docs. # 71-10 at 1–5, 71-14, 107 at 12–14.) Dr. Elliott is a certified urologist, professor of urology at the Mayo Clinic College of Medicine and Science, and a prolific, peer-reviewed author. (Doc. # 71-10 at 8–39.)

Defendants seek to exclude six general opinions of Dr. Elliott. (Docs. # 118, 107 at 12–14.) The court will analyze each in turn and determine, based upon Rule 702 and *Daubert* principles, whether they ought to be excluded.[2]

Opinion # 1: The Mesh in the TVT-O is Unsafe

In his expert report, Dr. Elliott opines that the mesh used in the Gynemesh Tension-free Vaginal Tape – Obturator (TVT-O) is unsafe to treat Stress Urinary Incontinence (SUI) because, among other things, it degrades which causes a variety of health complications. (Doc. # 71-10 at 101–21.) Defendants seek to exclude Dr. Elliott's statements that the TVT-O "should not be used in the pelvic floor" or "implanted in the human body for use in the treatment of SUI" (*see* Doc. # 71-10 at 91, 101) because they assert that a 2019 academic article he co-published contradicts statements he made in his expert report about the TVT-O mesh. (Docs. # 71-14 at 2–4, 107 at 12.)

Any contradiction(s) between Dr. Elliott's expert report and subsequent research would undermine his credibility as a witness, but this alleged issue does not prevent him from testifying that TVT-O mesh is unsafe for treating SUI. *See In re Avandia Mktg., Sales Pracs. & Prod. Liab. Litig.*, No. 2007-MD-1871, 2011 WL 13576, at *9 (E.D. Pa. Jan. 4, 2011) (noting that alleged inconsistency in an expert's

[2] As emphasized at the status conference held on November 1, 2022 (Doc. # 174), where other courts have already examined Defendants' objections to Dr. Elliott's testimony, such prior examination will be viewed as persuasive.

opinions "goes to his credibility"). The credibility of Dr. Elliott's testimony regarding the TVT-O mesh is for the jury to determine with the benefit of context and cross-examination. As another court found, "[a]ny alleged inconsistencies between [Dr. Elliott's] current opinions and the opinions of the article are better addressed through cross-examination than exclusion." *Ellerbee v. Ethicon, Inc.*, No. 8:20-CV-1514-TPB, 2021 WL 2010641, at *2 (M.D. Fla. May 20, 2021); *see also Benestad v. Johnson & Johnson*, No. 20-60496-CIV, 2022 WL 5241005, at *6 (S.D. Fla. Mar. 30, 2022). "While the 2019 article is fodder for cross-examination, it does not render Dr. Elliott's general opinion on the TVT-O unreliable." *Geery v. Ethicon, Inc.*, No. 6:20-CV-1975-RBD, 2021 WL 2580144, at *6 (M.D. Fla. Apr. 9, 2021). As a result, Defendants' *Daubert* motion is due to be denied as to Dr. Elliott's first general opinion.

Opinion # 2: Defendants Failed to Test and Conduct Studies

Dr. Elliott asserts that Defendants failed to conduct various studies and tests on the TVT-O to ensure its safety. (Doc. # 71-10 at 117–18, 122–23, 127.) Defendants seek to exclude these general opinions on two grounds. First, Defendants argue that Dr. Elliott's 2019 article refutes his opinions about deficient testing, rendering them unreliable. (Doc. # 71-14 at 8.) Similar to Dr. Elliott's first general opinion, this argument is best left for trial and cross-examination. *See Ellerbee*, 2021 WL 2010641, at *2; *Benestad*, 2022 WL 5241005, at *6.

Second, Defendants argue that Dr. Elliott is unqualified to offer these opinions because "there is nothing in Dr. Elliott's background that would provide him with specialized knowledge about the testing that Ethicon or other medical device manufacturers supposedly should have performed." (Docs. # 71-14 at 5–7, 107 at 12.) Specifically, among other things, Defendants state that "[b]ecause Dr. Elliott has no relevant experience, he is unable to identify a single rule or regulation that would require Ethicon to conduct different testing." (Doc. # 71-14 at 6.) Rather, "his opinion apparently is based purely on unscientific personal belief." (Doc. # 71-14 at 6.)

Defendants point to prior decisions where courts prevented other experts from testifying about testing because of their lack of qualifications. *Carlson v. Bos. Sci. Corp.*, No. 2:13-CV-05475, 2015 WL 1931311, at *15 (S.D.W. Va. Apr. 28, 2015) (finding that since "Dr. Shull has no demonstrated training in, knowledge about, or experience with the design of clinical trials or the process of testing medical devices, his opinion falls short of Federal Rule of Evidence 702 and cannot be admitted"); *Huskey v. Ethicon*, *Inc.*, 29 F. Supp. 3d 691, 705 (S.D.W. Va. 2014) (finding that Dr. Rosenzweig was "not qualified to opine that Ethicon's testing was insufficient" because he lacked "any experience and knowledge on the appropriate testing a medical device manufacturer should undertake").

Plaintiff responds that Defendants misstate what Dr. Elliott plans to testify about. (Doc. # 71-15 at 7 (citing Doc. # 71-9 at 13–14).) According to Plaintiff, Dr. Elliott "has no intention to opine on the *legal adequacy* of the testing conducted by [Defendants], but rather on the *factual* underpinnings of whether or not testing was conducted." (Doc. # 71-19 at 13 (emphasis in original).) Based on his "review of the literature and internal" documents of Defendants, Dr. Elliott "observed that [Defendants], when confronted with safety issues, did not conduct testing." (Doc. # 71-9 at 13.) Dr. Elliott does not seek to opine about whether Defendants violated a law or regulation by failing to test but "rather the factual and undisputed point that, when safety issues arose, [Defendants] did not conduct testing." (Doc. # 71-9 at 13–14.)

Other courts have faced nearly identical arguments and have found that Dr. Elliott is unqualified to testify about what testing Defendants should have performed. In *Wiltgen v. Ethicon, Inc.*, the Northern District of Illinois granted Defendants' *Daubert* motion to exclude Dr. Elliott from providing opinions on the "regulatory or legal adequacy of [Defendants'] testing." No. 12-CV-2400, 2017 WL 4467455, at *5–6 (N.D. Ill. Oct. 6, 2017).[3] In *Tedder v. Ethicon, Inc.*, the Northern District of Florida held that "Dr. Elliott may not testify about regulatory research or testing

[3] The product at issue in *Wiltgen* was the Gynecare Tension-Free Vaginal Tape (TVT) and not the TVT-O. 2017 WL 4467455, at *6 & n.4. But the court's reasoning is, nonetheless, persuasive.

requirements or what research or testing he contends Ethicon should have conducted." No. 3:20CV5611-MCR, 2022 WL 970693, at *4 (N.D. Fla. Mar. 31, 2022).

But this does not mean that Dr. Elliott is completely barred from testifying about Defendants' testing of the TVT-O. "Whether Ethicon should have researched or performed tests after becoming aware of complications . . . is a factual matter that does not implicate Rule 702." *Tedder*, 2022 WL 970693, at *4. Another court explained the relevant distinction: "Dr. Elliott will be precluded from opining on what research and testing Ethicon should have done," but "[t]his does not prevent Dr. Elliott from noting when studies were not conducted by Ethicon." *Geery*, 2021 WL 2580144, at *6 & n.4.

As a result, to the extent that Dr. Elliott seeks to opine on the regulatory or legal adequacy of Defendants' testing of the TVT-O or whether Defendants *should* have conducted certain tests prior to the discovery of complications with the TVT-O, Defendants' *Daubert* motion regarding Dr. Elliott's second general opinion is due to be granted. But Dr. Elliott may testify that certain tests should have been performed after Defendants discovered complications with the TVT-O. And he may generally observe when studies were not conducted based on his review of the record.

Opinion # 3: The Polypropylene Used Includes a Risk of Being Carcinogenic

In his expert report, Dr. Elliott makes a single statement that "Ethicon should have informed physicians (and therefore patients) that the MSDS [material safety data sheet] for its polypropylene noted a risk of carcinogenicity with the use of the plastic." (Doc. # 71-10 at 123.) Defendants seek to preclude Dr. Elliott from giving such testimony because it is "misleading[,] [irrelevant,] and confusing as well as highly prejudicial." (Docs. # 71-14 at 10, 107 at 12–13.) Defendants also argue that this opinion is, once again, contradicted by his 2019 article. (Doc. # 71-14 at 10.) And, once again, to the extent that there is any inconsistency, this argument is best left for trial where Defendants may use the article to cross-examine Dr. Elliott. *See Ellerbee*, 2021 WL 2010641, at *2; *Benestad*, 2022 WL 5241005, at *6.

Plaintiff responds that the evidence that the polypropylene mesh "led to local sarcomas in lab rats"—"startling information"—"was never provided to physicians." (Doc. # 71-15 at 6.) According to Plaintiff, "the carcinogenic properties of polypropylene . . . was a noted risk not disclosed to physicians by [Defendants], and Dr. Elliott is qualified to identify noted risks and explain that the risks on the MSDS were not included on the relevant IFUs [Instructions for Use] or in Defendants' product literature." (Doc. # 71-15 at 7.)

Evidence is relevant if "it has any tendency to make a fact" of consequence "more or less probable than it would be without the evidence." Fed. R. Evid. 401.

But even relevant evidence is excluded "if its probative value is substantially outweighed by . . . unfair prejudice . . . ." Fed. R. Evid. 403. In *Garvin v. Ethicon, Inc.*, the Western District of Kentucky faced nearly identical arguments about Dr. Elliott's third opinion. No. 3:20-CV-714-BJB, 2022 WL 2910024 (W.D. Ky. July 22, 2022). The Western District found that "[t]he little probative value of this testimony is 'substantially outweighed' by the risk of unfair prejudice." *Id.* at *11. "In light of the low probative value and high likelihood of unfair prejudice, the Court excludes this opinion." *Id.*

The Western District of Kentucky's analysis is persuasive, and Plaintiff does not convincingly argue otherwise. As a result, Defendants' *Daubert* motion is due to be granted as to Dr. Elliott's third general opinion.

Opinion # 4: Defendants Failed to Disclose or Downplayed the Adverse Effects of the TVT-O in their IFUs

Dr. Elliott asserts that Defendants' IFUs failed "to disclose important safety and risk information to physicians thereby compromising the ability for all levels of surgeons to adequately and appropriately [secure] consent [from] their patients prior to the implantation of the TVT-O device." (Doc. # 71-10 at 124.) According to Dr. Elliott, "[t]he IFU for the TVT-O fails to disclose numerous adverse risks, safety information and warnings that are associated with the product, including, among others, the following: Death, pain, chronic pelvic pain, permanent dyspareunia,

permanent sexual dysfunction, injury and pain to partner during sexual intercourse, negative impact on sexual function, vagina anatomic distortion, inability to remove the device, permanent risks for erosions, surgical interventions, development of worsening incontinence and urinary dysfunction." (Doc. # 71-10 at 125.) And "internal documents and the depositions of Ethicon employees reveal[] that [Defendants] [were] aware of these risks before or at the time the TVT-O was first marketed and sold." (Doc. # 71-10 at 125.) Moreover, Defendants changed the TVT-O substantially in 2015, "add[ing] numerous new risks and warnings for the first time[.]" (Doc. # 71-10 at 127.)

Defendants request that the court limit Dr. Elliott to testifying about risks of implanting the TVT-O and whether those risks were included in the IFU because he is unqualified to opine about what should have been included in the IFU. (Docs. # 107 at 13, 71-14 at 11.) Defendants state "that '[w]hile an expert who is an obstetrician and gynecologist may testify about the specific risk of implanting mesh and whether those risks appeared on the relevant IFU, the same expert must possess additional expertise to offer expert testimony about what information should or should not be included in an IFU.'" (Doc. # 71-14 at 11 (quoting *In re: Ethicon Inc.*, No. 2327, 2016 WL 4582220, at *3 (S.D.W. Va. Sept. 1, 2016), *adopted sub nom. In re Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, No. 2327, 2017 WL 4769671 (S.D.W. Va. July 21, 2017)). Because "Dr. Elliott's curriculum vitae does not

identify any additional expertise to render an opinion about the adequacy of Ethicon's IFUs," the court should preclude Dr. Elliott from testifying "about whether other risks 'should or should not be included in an IFU.'" (Doc. # 71-14 at 11–12 (quoting *In re: Ethicon, Inc.*, No. 2:12-MD-02327, 2016 WL 4536885, at *2 (S.D.W. Va. Aug. 30, 2016).) Plaintiff responds that Dr. Elliott has such additional expertise because he has "extensive experience in the testing and development of medical devices," owns a patent, and "trains . . . residents" about IFUs. (Doc. # 71-15 at 9.)

In *Garvin*, the Western District of Kentucky addressed an identical argument from the defendants and an identical response from the plaintiff. 2022 WL 2910024, at *11–12. After noting that the MDL court had previously determined that Dr. Elliott did not possess the additional expertise to testify about what should be included in the TVT-O IFU and that it "generally will not 'revisit prior decisions . . . in the absence of extraordinary circumstances such as where the initial decision was clearly erroneous and would work a manifest injustice,'" the Western District of Kentucky rejected the plaintiff's argument that he had such additional expertise. *Id.* at *12 (quoting *Christianson v. Colt Indus. Operating Corp.*, 486 U.S. 800, 817 (1988) (quotation omitted)). As a result, the Western District "exclude[d] testimony on what should be included in an IFU, but permit[ed] Dr. Elliott to testify regarding specific risks and whether they were included in the IFU." *Id.*

There is an insufficient evidentiary foundation about Dr. Elliott's reliance on the TVT-O IFU to make a full determination at this time. Dr. Elliott is permitted to testify about specific risks created by the TVT-O and whether those risks were included in the TVT-O IFU. But a ruling on whether he can testify about what should be included in the IFU is deferred. This aspect of Defendants' *Daubert* motion is reserved for trial.

Opinion # 5: There are Safer, Feasible Alternatives to the TVT-O Mesh

Dr. Elliott states that certain procedures are safer alternatives than the TVT-O for women with SUI. (*See* Doc. # 71-10 at 95–96.) Defendants raise two objections to Dr. Elliott's proposed testimony: it is irrelevant (Docs. # 71-14 at 12–15, 107 at 13); and comparing "TVT Devices with traditional surgical procedures is unreliable" (Docs. # 71-14 at 15–19, 107 at 14). As to Defendants' relevance argument, the MDL court previously reserved ruling "until trial." (Doc. # 71-7 at 8.) As to Defendants' unreliability argument, the MDL court observed that "the reliability of this expert testimony is heavily dependent on Dr. Elliott's clinical experiences" and reserved ruling on whether such testimony was reliable "until further testimony may be offered and evaluated firsthand at trial." (Doc. # 71-7 at 8–9.) There is no reason to revisit this prior decision of the MDL court. *See Christianson*, 486 U.S. at 817. While it is likely that this testimony will be allowed,

Defendants' *Daubert* motion is reserved for trial as to Dr. Elliott's fifth general opinion.

Opinion # 6: Lightweight, Large-Pore Is Safer Than Heavyweight, Small-Pore Polypropylene Mesh

Dr. Elliott asserts that lightweight, large-pore polypropylene mesh is superior in terms of health outcomes when compared to heavyweight, small-pore polypropylene mesh, which is what Defendants use in the TVT-O. (Doc. # 71-10 at 105–11, 123–24.) Defendants argue that Dr. Elliott ought to be precluded from testifying about the negative side effects of heavyweight as opposed to lightweight mesh because his testimony is unreliable. (Doc. # 71-14 at 20 (citing Doc. # 71-8 at 7–10).)

The MDL court previously addressed whether Dr. Elliott's testimony was reliable regarding "alternative designs (e.g., mesh with larger pore size or less weight)." (Doc. # 71-7 at 9.) Like with its decision regarding the reliability of Dr. Elliott's testimony about alternative procedures, the MDL court stated that "the lynchpin of Dr. Elliott's testimony [about alternative designs] is his experience." (Doc. # 71-7 at 10.) As a result, the MDL court said that it was "without information sufficient to assess whether [Dr. Elliott's experience] is a reliable foundation." (Doc. # 71-7 at 10.) So, the MDL court reserved ruling on Defendants' objection "until

further testimony may be offered and evaluated firsthand at trial." (Doc. # 71-7 at 10.)

Because there is no reason to revisit this prior decision of the MDL court, *see Christianson*, 486 U.S. at 817, Defendants' *Daubert* motion is reserved for trial as to Dr. Elliott's sixth general opinion.

III. CONCLUSION

For the reasons provided above, it is ORDERED that Defendants' *Daubert* motion (Doc. # 71-10) is GRANTED in part, DENIED in part, and DEFERRED in part.

DONE this 8th day of December, 2022.

/s/ W. Keith Watkins
UNITED STATES DISTRICT JUDGE